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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/938,901 | 08/24/2001 | Seiki Kuramitsu | 11283-013001 | 5458 |
| 20985 | 7590 | 03/24/2004 | EXAMINER | |
| FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081 | | | | MARVICH, MARIA |
| ART UNIT | | PAPER NUMBER | | |
| | | 1636 | | |

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 09/938,901 | KURAMITSU ET AL. | |
| Examiner | Art Unit | | |
| Maria B Marvich, PhD | 1636 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 January 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 5-37 is/are pending in the application.
4a) Of the above claim(s) 5-31 and 33-35 is/are withdrawn from consideration.

5) Claim(s) 1,2,36 and 37 is/are allowed.

6) Claim(s) 32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 August 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/15/02
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: *Notice to Comply.*

DETAILED ACTION

This office action is in response to an Amendment filed 1/23/04. Claims 3-4 have been cancelled and claims 36-37 have been added. Claims 1-2 and 5-37 are pending. Claims 5-31 and 33-35 have been withdrawn.

Information Disclosure Statement

An IDS filed 1/15/02 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

This application is in condition for allowance except for the following formal matters:

Sequence Compliance

Figures 5, 14, 17, 27 and 34 contain sequences that are not accompanied by SEQ ID NOs. The sequence in figure 17 appears to be contained in the sequence listing. It would be remedial to insert the sequence identifier into the legend. However, the sequences in figure 5, 14, 27 and 34 do not appear to be included in the sequence listing. It would be remedial to submit a substitute sequence listing adding these sequences and to insert the sequence identifiers into the figure legends. A substitute computer readable format and a letter stating that the paper copy and CRF are the same and contain no new matter must accompany the substitute sequence listing. This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Drawings

Figure 13 is objected to under 37 CFR 1.83(a) because it fails to show any details as described in the specification. The SDS Page gel is said to indicate the presence of HIS10-RecJ. However, there are no visible details as the image is completely black. MPEP § 608.02(d). It would be remedial to submit a substitute figure.

Claim Objections

Claim 32 is objected to because of the following informalities: "An" is grammatically incorrect and should be "A". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action filed 9/23/03 and restated below.**

Applicants claim a genus of fusion proteins comprising an amino acid or a subsequence of SEQ ID NO: 2.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose SEQ ID NO:2 that has DNA repair activity. An amino acid sequence or subsequences or parts of SEQ ID NO: 2 are not disclosed that have DNA repair activity. Neither applicant nor the prior art provide a correlation between the structure of the recited sequences and their DNA repair activity. Given the diversity and large size of the genus of amino acids, subsequences or parts of SEQ ID NO: 2, and the inability to determine which will also have DNA repair activity, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by White et al. **This rejection is maintained for reasons of record in the office action filed 9/23/03 and restated below.**

White et al disclose an amino acid sequence from *Deinococcus radioduran* that is 39.4 percent homologous to the amino acid sequence disclosed in SEQ ID NO:2. Claims 1 and 2 recites that the isolated protein comprises/consists of an amino acid of SEQ ID NO:2. While claim 32 recites a fusion protein that is a subsequence of a first amino acid sequence. Given the percent homology between the sequence taught by White and that of SEQ ID NO: 2, the nucleotide sequence of White et al. reads on “an amino acid sequence” or “a subsequence” of the instant invention. Claim 3 recites an isolated protein encoded by a nucleic acid that hybridizes under stringent conditions. Applicant teaches that “stringent hybridization” refers to hybridizations or wash conditions under which nucleic acid will primarily hybridize to its target subsequence (page 25, line 23-27). A part of the sequence of White et al that is homologous to a part of the sequence of the instant invention would necessarily hybridize to the sequence of the instant invention. Therefore, the nucleotide sequence of the sequence taught by White et al. would under hybridize under the conditions as defined in the specification of the instant invention to the nucleic acid sequence of SEQ ID NO 2.

It would be remedial to recite that the isolated protein comprises or consists of the amino acid sequence of SEQ ID NO: 2.

Conclusion

Claims 1-2 and 36-37 are allowed.

Claim 32 is rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

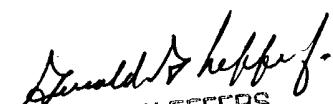
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

March 9, 2004


GERRY LEFFERS
PRIMARY EXAMINER